

# **Protocol for development of a reporting guideline (TRIPOD-AI) and risk of bias tool (PROBAST-AI) for diagnostic and prognostic prediction model studies based on artificial intelligence**

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## **Abstract**

Introduction The Transparent Reporting of a multivariable prediction model of Individual Prognosis Or Diagnosis (TRIPOD) statement and the Prediction model Risk Of Bias ASsessment Tool (PROBAST) were both published to improve the reporting and critical appraisal of prediction model studies for diagnosis and prognosis. This paper describes the processes and methods that will be used to develop an extension to the TRIPOD statement (TRIPOD-artificial intelligence, AI) and the PROBAST (PROBAST-AI) tool for prediction model studies that applied machine learning techniques. Methods and analysis TRIPOD-AI and PROBAST-AI will be developed following published guidance from the EQUATOR Network, and will comprise five stages. Stage 1 will comprise two systematic reviews (across all medical fields and specifically in oncology) to examine the quality of reporting in published machine-learning-based prediction model studies. In stage 2, we will consult a diverse group of key stakeholders using a Delphi process to identify items to be considered for inclusion in TRIPOD-AI and PROBAST-AI. Stage 3 will be virtual consensus meetings to consolidate and prioritise key items to be included in TRIPOD-AI and PROBAST-AI. Stage 4 will involve developing the TRIPOD-AI checklist and the PROBAST-AI tool, and writing the accompanying explanation and elaboration papers. In the final stage, stage 5, we will disseminate TRIPOD-AI and PROBAST-AI via journals, conferences, blogs, websites (including TRIPOD, PROBAST and EQUATOR Network) and social media. TRIPOD-AI will provide researchers working on prediction model studies based on machine learning with a reporting guideline that can help them report key details that readers need to evaluate the study quality and interpret its findings, potentially reducing research waste. We anticipate PROBAST-AI will help researchers, clinicians, systematic reviewers and policymakers critically appraise the design, conduct and analysis of machine learning based prediction model studies, with a robust standardised tool for bias evaluation. Ethics and dissemination Ethical approval has been granted by the Central University Research Ethics Committee, University of Oxford on 10-December-2020 (R73034/RE001). Findings from this study will be disseminated through peer-review publications. PROSPERO registration number CRD42019140361 and CRD42019161764.